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10/529,156	12/14/2005	Patrick Trotter	JJM0623USPCT	6568

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EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,156	TROTTER ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-6 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Priority

Acknowledgment is made of applicants' claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the British application was filed with the USPTO on Mar. 24, 2005. The instant application was granted the foreign priority date of Oct. 1, 2002. See MPEP § 201.15.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. Claim 3 contains sequences that are encompassed by the sequences rules and require sequence identifiers (SEQ ID numbers). Applicants are required to either amend the claim with the corresponding SEQ ID numbers. Applicants'

cooperation is requested in reviewing the entire disclosure for additional sequences to ensure that the application is in sequence compliance.

APPLICANT IS GIVEN THE TIME ALLOTED IN THIS OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six-month statutory period. Direct the response to the undersigned.

Claim Objections

Claim 2 is objected to because of the following informalities: the phrase "the one or more" should be inserted between the words "the" and "non-elastase" in line one of the claim to more properly reflect the claim language of claim 1.

Claim 2 is objected to because of the following informalities: the abbreviation "MMP" should be written-out as "matrix metalloproteinase" at its first use for clarity in this claim. Appropriate correction is required.

Claim 5 is objected to because the recitation "1 or 4" has been struck through. Thus, it is not apparent from which claim the claim depends.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, it is not clear whether the phrase "...preferably the 72kDa gelatinase (MMP2), the 92kDa gelatinase (MMP9), matrilysin or metalloelastase" is a limitation or whether it is merely listing disclosed examples and/or embodiments. Similarly, it is not clear whether the phrase "...preferably no longer susceptible" in claim 3 is a limitation or whether it is merely listing disclosed examples and/or embodiments. Description of examples or preferences is properly set forth in the specification rather than the claims. Since it is unclear whether these phrases are limitations, and thus part of the claimed invention, the phrases render the claims indefinite. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over CALDWELL (U.S. 5,856,245; Issued Jan. 5, 1999) in view of WEST (U.S. 2003/0012816; Filed Sep. 4, 2001) and HALLE (U.S. 2003/0073657; Filed Apr. 30, 2002).

1. Caldwell discloses barrier webs and fabrics for use in wound dressings (abstract; column 18, lines 18-21; column 51, lines26-34; claim 17). Caldwell teaches that certain proteins, such as elastin, are especially useful as wound healing agents in the wound dressings of the invention (column 52, lines 57-60; claims 21, 22, and 46). Caldwell further teaches that the wound dressings comprise an antimicrobial agent (column 16, lines 27-47; column 33, lines 52-56; Table beginning in column 34, especially the section entitled 'Therapeutic Agents' in column 37; claims 23-25). Additionally, Caldwell teaches that the material of the invention can be used to release an agent (e.g. a

therapeutic agent) from the material through degradation of the material and that such degradation can occur through a variety of means, known to those of skill in the art (column 38, lines 34-52).

2. Caldwell does not teach the use of *modified* elastin.

3. West discloses biodegradable hydrogel wound dressings that release therapeutic agents as they are broken down (abstract; paragraph [0081]). West teaches that the compounds to be released include, *inter alia*, antibiotics and can be physically entrapped, bound to the hydrogel polymer, or actually form part of the polymeric material (paragraphs [0013] and [0066]), and also teaches that the time required for the polymer to degrade can be tailored by altering the degradation rates of the polymer (paragraph [0045]). West teaches that biodegradable regions can be constructed from polymers susceptible to enzyme degradation, including peptides (paragraph [0047]), and further teaches that the biodegradable regions are preferably separated from the polymerizable (i.e. non-degradable) regions to facilitate uniform degradation *in vivo* (paragraph [0050]). West teaches that the dressing materials are particularly useful for controlled release drug delivery, which may occur by diffusion of the active agent or release of the active agent as the polymer is degraded and that degradation of the polymer facilitates the controlled release (paragraph [0095]). West further teaches that the amount of active agent released by the polymers can be tailored by altering the nature and ratio of polymer components (paragraphs [0097] and [0139]). Complimentary to the teachings of Caldwell, West teaches that healing of chronic

wounds may be hampered by proteases since they degrade growth factors that would otherwise promote healing (paragraph [0008]).

4. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use modified elastin that was either more or less susceptible to linked to poor wound healing when applying a wound dressing to a wound, particularly a chronic wound. One would have been motivated to do so to provide the wound dressings of Caldwell with a means adjust the time for controlled release of an active agent. The artisan would have a high expectation of success in doing this since Caldwell suggests the that the dressings are useful for this purpose (column 37, lines 57-64) and since West teaches that that polymers may be peptide based (paragraph [0039]). Further, it is well within the skill of the ordinary artisan to select and modify the appropriate sites of elastin as necessary, making the elastin either more or less susceptible, to adjust the time it would take to degrade in a given type of wound.

5. Neither Caldwell nor West discloses specific non-elastase proteinases.

6. However, Halle discloses peptide inhibitors of proteases, particularly metalloproteases, and their use in the treatment of wounds (abstract; paragraph [0004]). Halle teaches that these protease inhibitors are useful in dressings, compresses, and gels (paragraph [0064]). Halle teaches that the levels of the gelatinases MMP2 and MMP9 are increased in chronic wounds (paragraph [0005]) and that excessive proteolytic activity is responsible for the poor healing of chronic wounds (paragraph [0007]).

7. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to inhibit the activity of the proteinases linked to poor wound healing when applying a wound dressing to a wound, particularly a chronic wound. One would have been motivated to do so in order to provide treatment to a wound that is likely to have an excess of proteinase activity, as in the case of chronic wounds as taught by Halle. Therefore if an artisan wanted to produce a wound dressing for chronic wounds with controllable active agent release, one would have been motivated to modify the elastin of Caldwell's dressings to be either more or less susceptible to proteases such as MMP2 and/or MMP9. Thus, the combination of Caldwell, West, and Halle renders claims 1, 2, 4, and 6 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Claims 1, 3, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caldwell in view of West and Halle as applied to claims 1, 2, 4, and 6 above,

and further in view of McGRATH (WO 02/053172; Published Jul. 11, 2002; last reference on sheet 1 of IDS dated 11/28/05) and MECHAM (R. P. Mecham, *et al.* (1997) J. Biol. Chem. 272(29); 18071-18076; 1st reference on sheet 2 of IDS dated 11/28/05) .

8. While the claim from which claim 5 depends is unspecified, claim 5 has been interpreted to depend from claim 4 for the purposes of the following rejections.

9. The teachings of Caldwell, West, and Halle are presented above. None of the references explicitly teach modification of the primary sequence of elastin.

10. However, McGrath discloses the use of modified peptides as specific MMP (e.g. gelatinase) inhibitors useful in the treatment of chronic wounds (page 2, last paragraph; page 7, last paragraph; page 13, 2nd paragraph). For example, McGrath teaches that known MMP regulators are peptide derivatives based on naturally occurring amino acids that are analogues of the cleavage site in the native protein (page 5, first paragraph), and can be created by modifying the amino acid sequence of natural peptide inhibitors (page 6, top paragraph). McGrath teaches designing peptides that bind selectively to one or more protease(s), for example the gelatinase MMP9 (page 8, last two paragraphs; page 14, middle paragraph), and thereby inhibit degradation of elastin (page 9, 5th paragraph). Additionally, McGrath teaches the inclusion of such peptide-based inhibitors in wound dressings such as hydrogels (page 10, 4th paragraph; page 17, 2nd paragraph; claims 17 and 55). Further, McGrath discloses inhibitory peptide sequences that match and/or significantly overlap with those recited in instant claim 3, for example SEQ ID No 3 (pages 15 and 16).

11. It is noted that the elastase sites susceptible to cleavage by MMP2 and MMP9 and the particular amino acid preference in these sites were known at the time of the invention as taught by Mecham (abstract; Figures 3 and 4; discussion on pages 18075-18076).

12. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention modify the primary sequence of elastin at these sites in the wound dressings taught by Caldwell as a means of controlling the release of an active agent from the dressing. It would have been obvious for a skilled artisan to do so since Mecham teaches the specific sites of cleavage targeted by MMP2 and MMP9 and since McGrath teaches the design of MMP inhibitory peptides based on similar sequences. The ordinary artisan would recognize that modification at these sites would inhibit degradation of elastin by these MMPs and would provide the necessary control of degradation for a controlled release polymer as taught by West. One would have had a high expectation of success in doing so based on the teachings of the references. Thus, claims 1, 3, and 5 are rendered obvious over the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application

or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application No. 10/529,157

Claims 1, 2, and 6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 10, and 13 of copending Application No. 10/529,157. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '157 claims renders obvious that of the instant claims. The difference between the two claim sets is that '157 claim 1 does not recite modified elastin. However, modified elastin is a cross-linked polymer that comprises oligopeptide sequences that are cleavable by a protease associated with wound fluid. It is noted that '157 claim 10 recites a gelatinase and '157 claim 13 recites the species of therapeutic agent of instant claim 6. Thus, the genus recited by '157 claim 1 encompasses that of instant claim 1, this element, and thus the entire scope of the indicated instant claims is rendered obvious.

As set forth above, claims 1, 2, and 6 are directed to an invention not patentably distinct from claims 1-4, 10, and 13 of commonly assigned 10/529,157.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/529,157, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was

made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

U.S. Patent Application No. 10/497,442

Claims 1, 2, and 6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 13, and 15-17 of copending Application No. 10/497,442. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '442 claims renders obvious that of the instant claims. The difference between the two claim sets is that '442 claim 1 does not recite modified elastin, but rather recites a substrate for an enzyme from an infected or chronic wound. However, modified elastin is encompassed by this limitation. It is noted that the gelatinases recite in instant claim 2 are also encompassed by the genus 'proteases' recited in '442 claim 1. Since, the genus recited by '442 claim 1 encompasses that of instant claim 1, this element, and thus the entire scope of the indicated instant claims is rendered obvious.

As set forth above, claims 1, 2, and 6 are directed to an invention not patentably distinct from claims 1-4, 13, and 15-17 of commonly assigned 10/497,442.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/497,442, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

U.S. Patent Application No. 10/579,897

Claims 1, 2, 5, and 6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 6, 7, 14, and 17 of copending Application No. 10/579,897. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '897 claims renders obvious that of the instant claims. The difference between the two claim sets is that '897 claim 1 does not recite modified elastin, but rather recites a medically acceptable polymer. However, modified elastin is encompassed by this

limitation. It is noted that the gelatinases recite in instant claim 2 are also encompassed by the genus 'protease' recited in '897 claim 1. Since, the genus recited by '897 claim 1 encompasses that of instant claim 1, this element, and thus the entire scope of the indicated instant claims is rendered obvious.

As set forth above, claims 1, 2, 5, and 6 are directed to an invention not patentably distinct from claims 1-3, 6, 7, 14, and 17 of commonly assigned 10/579,897.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/579,897, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643